DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-771/S-020

Whitehall-Robins
Attention: Ms. Sharon Heddish
Director, Regulatory Affairs
Five Giralda Farms
Madison, NJ 07940-0871

Dear Ms. Heddish:

Please refer to your supplemental new drug application (NDA) dated November 21, 2000, received November 24, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advil Cold & Sinus Tablets/Caplets, Dristan Sinus, Advil Flu & Body Ache Caplets (ibuprofen and pseudoephedrine tablets and caplets).

This supplemental new drug application provides for the revised labeling in Drug Facts format.

We have completed the review of this supplemental new drug application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling dated November 21, 2000, with the minor editorial revisions listed below. Accordingly, the application is approved effective on the date of this letter provided that:

1. The promotional statement "advanced formula for flu relief" on the principal display panel (PDP) must be removed. The active ingredients and the quantities for each ingredient are the same as the Advil Cold & Sinus product and appear to offer no special advantage for flu relief. This promotional statement must be substantiated by data in order to be allowed on the PDP.

2. The flag "New" should be deleted, as only the name is new, to avoid misleading the consumer to mistaking that this is a new product.

Also, at the time of the next printing or within 180 days, whichever comes first, the labeling should be further revised as per the attached prototype.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (immediate container and carton labels submitted November 21, 2000). These revisions are terms of the NDA approval. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. For administrative purposes, this submission should be designated "FPL for approved NDA 19-771." Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of the labeling may be required.

If you have any questions, call Babette Merritt, Project Manager, at (301) 827-2222.

Sincerely,

Linda M. Katz, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure